Clinical Oversight Review Board (CORB) Criteria for Prescribing / Criteria-Based Consultation (CBC) Criteria for Coverage

CRITERIA FOR PRESCRIBING

Tolvaptan (Jynarque)

Non-formulary Tolvaptan (Jynarque) requires a clinical review. Appropriateness will be based on the following criteria:

- **Criteria 1**
  - Is the prescriber a Nephrologist?
  - Is the patient at least 18 years of age?

- **Criteria 2**
  - Patient has diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed by one of the following:
    - Ultrasonography
    - With family history: several (3 cysts per kidney)
    - Without family history: 10 cysts per kidney
    - Magnetic resonance imaging (MRI) or computed tomography (CT) scan
    - With family history: 5 cysts per kidney
    - Without family history: 10 cysts per kidney

- **Criteria 3**
  - High risk of disease progression defined as has typical (Class 1) ADPKD classified as 1C, 1D, or 1E using the Mayo ADPKD Classification assessment?: And one of the following:
    - Age 18 to 50 years with eGFR of at least 60 mL/min/1.73m^2^ AND
    - Total kidney volume (TKV) at least 750 mL
    - Age 18 to 55 years with eGFR of at least 25 to 65 mL/min/1.73m^2^ AND
    - Age 56 to 65 years with eGFR of at least 25 to 44 mL/min/1.73m^2^ AND
    - eGFR decline greater than 2 mL/min/1.73m^2^ per year

Note(s):
* The first available treatment to slow the decline in kidney function in adults with rapidly progressing ADPKD, to prolonging time to end-stage renal disease (ESRD), dialysis, and transplantation.
* Two pivotal randomized, controlled trials were submitted in the application: TEMPO 3:4 and REPRISE.
* Access is only through Specialty Pharmacy (Panther Rx) which requires enrollment in Jynarque REMS due to high risk of severe and potentially fatal drug-induced liver injury. A boxed warning advises that monthly liver function tests are required for the first 18 months of therapy and every 3 months thereafter. Specifically per product information: ALT, AST, and bilirubin: Prior to therapy initiation, at 2 and 4 weeks after initiation, monthly for 18 months, and every 3 months afterwards.
* The monthly cost per patient is approximately $13,040.